

# Gray Market in the Dental Industry

*Confronting unauthorized distribution channels that threaten patient safety and dentist integrity*

## **Executive Overview**

The gray market operates outside the dental industry's established supply chain. While not inherently illegal, gray market distribution channels are often the same channels used to carry counterfeit or other black market products.

Importantly, the dental products sold through gray market distributors may not live up to the expectations of dentists or patients. Products may be past their expiration date, recalled, fall short of industry and government standards, and present patient safety and dentist liability risks.

Select manufacturers, distributors and industry professionals are raising concerns about the potentially unsafe gray market and the illegal black market. These companies are working to develop solutions to protect patients and dentists through enhanced supply chain integrity efforts. Still, much work remains to educate dentists, dental businesses and patients about the dangers of heavily discounted gray and black market dental products, and to better secure dental supply chains.

## **What Is the Gray Market?**

A gray market, also known as a parallel market, is an unauthorized and non-secure distribution channel through which products and materials are sold. Unlike black markets, which are used to distribute stolen, defective or counterfeit products, and are by definition illegal, gray markets exist under a much less-defined jurisdiction.

Gray markets can be used to distribute legal and legitimate products that have been recalled or expired. But gray markets may also include goods that have been diverted from a country in which they are approved for use into a separate country in which they are not approved. In these instances, the products may not meet the industry standards or

comply with government regulations in the countries where they are being sold, making them illegal.

*"A significant concern is that products available on the gray market may be defective products that have been diverted from planned destruction or products that may have been recalled."*

- U.S. Food and Drug Administration

Beyond the products themselves, gray market distribution channels may fall short of the standards and practices used by trusted, authorized sources. As a result, products which require precision and care in their distribution may be more likely to be mishandled during storage or transportation, such as not being kept within a required temperature range.

## *A Global Concern*

Gray markets exist across multiple industries, driven primarily by their low-cost appeal, the prevalence of Internet commerce, and exporters or straw buyers looking for opportunities to turn a profit. Gray markets frustrate ethical businesses, industries and governments alike.

But there's also an adverse impact on consumers. For example, some of the world's top camera manufacturers have issued notices about purchasing less-expensive gray market cameras. The companies warn consumers that gray market cameras cannot be registered and may not be

compatible with local power outlets. They also warn that their warranties, technical support and rebates do not apply to gray market products.

### *Dental Industry Impact*

The \$6 billion dental industry is not immune to the global gray market. Products that are not directly sourced from trusted manufacturers, or that are not fully controlled and safely handled by authorized distributors throughout the supply chain, are making their way into dental offices and patients' mouths.

Approximately 15 percent of the U.S. dental market is gray or black, according to industry estimates.\* One manufacturer estimates that 5 to 8 percent of products that carry its label are either gray market or counterfeit products. \*\*

### **Gray Market Risks**

The lure of a good deal is rarely without a catch. That's especially true for deep-discounted gray market products. When products are repackaged and sold, how can you know what you're buying?

### *Endangering Patient Health*

First and foremost, gray market dental products and materials may jeopardize patient health and safety. Gray market goods that were not sourced from a trusted manufacturer or produced to satisfy the requirements of other markets, or that were mishandled in the supply chain inherently pose an increased risk to patient health.

### *Putting Your Reputation on the Line*

Patient injuries and subpar dental work resulting from the use of gray market goods threaten the reputations of the dentists and businesses that use them. The consequences may include the loss of patient trust, potential lawsuits, negative perceptions that spread through online reviews and social media, and even negative media stories. All of these can cause lasting reputation damage to a dental practice.

### *A Bargain Ripe With Financial Risk*

Gray market goods typically are not backed by the manufacturer. Potential dental rework or litigation resulting from gray market goods will all come at the dental business' expense. And any products that are found to be past their expiration date or below quality standards will most likely not be covered by a manufacturer's warranty. There are significant financial risks if a patient's health is endangered.

### **Identifying Gray Market Goods**

Dental products sold through the gray market may appear on the surface to be legitimate and approved products from trusted manufacturers. Here are some guidelines for identifying potential gray market products:

- **Cost:** The greatest appeal of gray market goods can also help identify them as such. Deeply discounted dental products, which are often found on the Internet, should immediately raise suspicion. And while cost alone can't pinpoint gray market products, the old adage applies: If it sounds too good to be true, it probably is.

- **Expiration Date:** Gray market distributors will sometimes sell products beyond their expiration dates. Check the product packaging to verify that the expiration date hasn't either expired or been altered in some way.
- **Packaging:** Gray market product packaging may appear similar to standard product packaging – possibly because it was produced by the same manufacturer but for a different market with different standards and regulations. Packaging issues such as missing or altered information, foreign languages and information intended for other markets should raise a red flag.
- **Seller:** Dental manufacturers generally list their authorized distributors on their websites and offer a telephone number to call. It's usually easy to determine if a seller is authorized. If the seller is not, it may be safest to purchase dental supplies through another source.

## **Securing the Dental Supply Chain**

A combination of ongoing efforts and new opportunities to act exists across the dental supply chain – from the point of manufacture to the point of sale.

### *Manufacturers*

Dental product manufacturers have multiple interests in protecting their supply chain integrity and the reputations of their brands. Importantly, they want to ensure patients are treated using only products that have been designed, tested and certified to meet the strict quality standards in the markets for which they are approved. Gray market sales may circumvent these consumer and manufacturer protections.

Some manufacturers have introduced more advanced product packaging designs that are less easy to replicate or invested in regionally appropriate packaging, labeling and product registration. Many use only authorized distributors that meet their requirements for procuring, controlling and handling products to help ensure dentists receive authentic products that work as advertised.

### *Distributors*

Distributors play a vital role in ensuring that dental customers and their patients receive legitimate and compliant dental products. Leading distributors are taking proactive action to increase customer awareness surrounding their supply chain integrity efforts and assuring dental customers that products are directly sourced from manufacturers.

Trusted distributors help protect product supply chains and ensure products are properly handled along the way. That means using distribution centers with climate-controlled environments, handling products properly, tracking expiration dates and establishing partnerships with shipping partners to secure deliveries.

*“We are taking a very public leadership position to work with our manufacturer partners to ensure products go directly from the manufacturer to an authorized distributor to the customer.”*

- Scott P. Anderson, Patterson Companies' Chairman, President and CEO

### *Dentists / Purchasers*

Armed with their purchasing power, dentists are on the frontlines in the protecting patients from potentially unsafe or defective gray market products.

The best action dentists can take is to be more rigorous in their purchasing habits. That can include researching products and suppliers prior to making purchasing decisions, more carefully scrutinizing suppliers of heavily discounted products, and using only the manufacturers' authorized distributors or trusted major distributors. If questions or doubts arise about a distributor, dentists shouldn't hesitate to contact the product's manufacturer.

### *Additional Pressures*

Manufacturers, distributors and dentists each have a role to play in ensuring supply chain integrity, but relying on these individual entities alone may not be enough.

A more effective approach may involve manufacturers, distributors, dentists and government regulators working collectively to adopt robust industry supply chain standards or certification. Such standards could mirror the FDA's recent efforts to establish a unique device identification (UDI) system for most medical devices.

The medical device industry's UDI system will assign unique ID tags to all Class I, II and III medical devices and their packages by September 2020. This effort aims to secure the medical-device supply chain and, ultimately, improve patient safety. Similarly, the [Dental Trade Alliance](#) is working to prepare dental manufacturers and distributors for UDI implementation on dental devices sold in the United States.

*"The UDI system requires manufacturers and distributors to assign bar codes to their products and equipment. These barcodes will include information identifying the name of the manufacturer, manufacturer's contact information, date of origin, lot number, date of shipment, the product's class (I, II or III device, risk classification), any expiration dates and other pertinent information."*

- Dental Trade Alliance

### **Summary**

Much work remains to address the gray market's threat to the dental industry. Combining efforts across the supply and demand chain – including manufacturers, distributors and dental purchasers working in concert with new government regulations – will help ensure that only **approved products**, produced by **trusted manufacturers** and supplied by **authorized distributors**, are used when caring for patients.

### **Learn More**

For more information on the dental gray market and its risks, visit [www.DentalSupplyIntegrity.com](http://www.DentalSupplyIntegrity.com).

**White Paper Source:** Patterson Companies, Inc.

### References

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\* "Shades of Gray" – Mentor, December 2013

\*\* "Are you using 'gray-market' or counterfeit dental products?" – Journal of American Dental Association, June 2010